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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,939	11/07/2001	Harold G. Craighead	1153.009US1	5674
21186	7590	04/18/2006	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.			SINES, BRIAN J	
P.O. BOX 2938			ART UNIT	
MINNEAPOLIS, MN 55402			PAPER NUMBER	

1743

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,939

Applicant(s)

CRAIGHEAD ET AL.

Examiner

Brian J. Sines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/2/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 35-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 35-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the claim recites the calculation of a refractive index. It is unclear as to how the claimed apparatus performs the recited function. A processing means for performing the calculation is not recited. Does the detector incorporate the use of a programmed processor in order to perform the recited calculation? The Court has held that programming creates a new machine because a general purpose computer in effect becomes a special purpose computer once it is programmed to perform particular functions pursuant to instructions from program software. *In re Alappat*, 31 USPQ2d 1545 (1994) (see MPEP § 2106). The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device (See MPEP § 2172.01).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

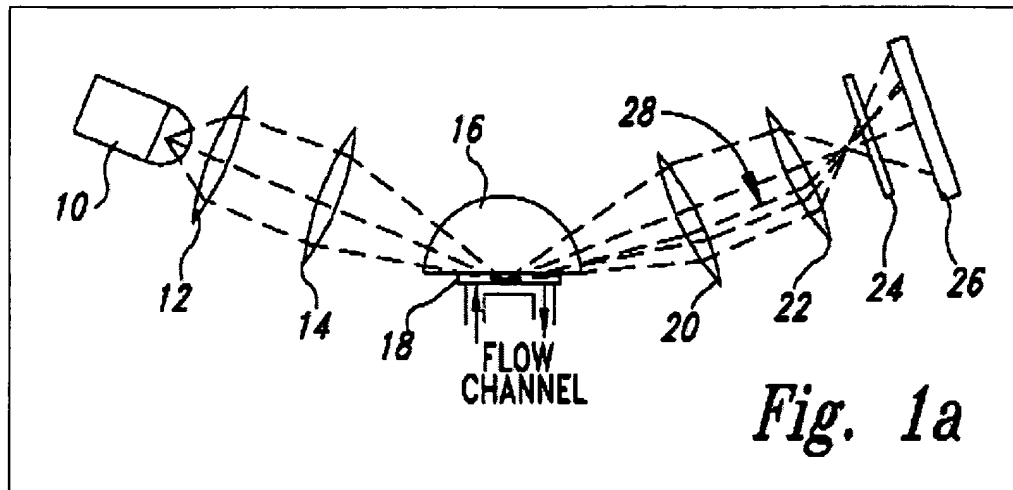
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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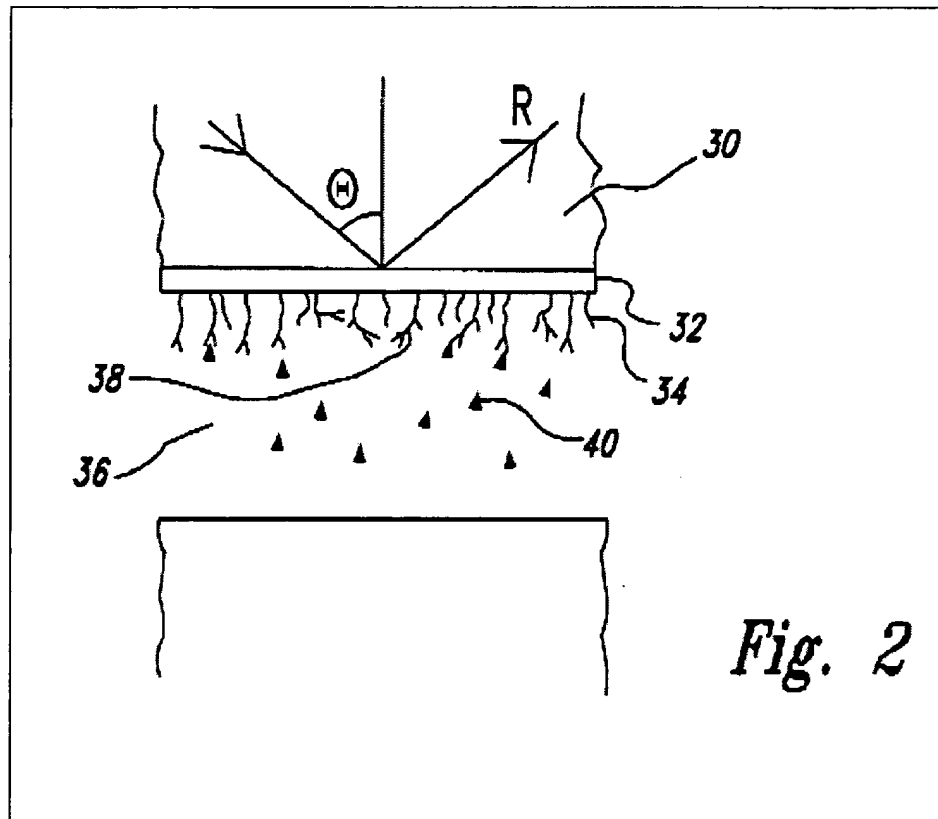
Claims 1 – 11, 13 – 25, 42, 43 & 45 – 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Malmqvist et al. (U.S. Pat. No. 5,965,456 A) (hereinafter “Malmqvist”).

Regarding claims 1 – 5, 7 – 11, 13 – 17, 20 – 25, 42, 43 & 47 – 50, as indicated in figure 1a, Malmqvist teaches a detection apparatus comprising: a duct, cavity, chamber means or flow channel comprising sidewalls; a glass support (30) coated with a thin gold film (32); a light source (LED 10); and a light receiver or optical sensor (photodetector 26) (see figure 1a). The Courts have held that things clearly shown in a reference patent drawing qualify as prior art features, even though they are unexplained by the specification. See *In re Marz*, 173 USPQ 25 (CCPA 1972).

Malmqvist teaches that the apparatus comprises transparent glass (see col. 5, lines 16 – 30). Thus, it is inherently anticipated that the device structure would be composed of glass. Malmqvist teaches the incorporation of an immobilized binding partner, such as an antibody (38), for detecting target analytes (see col. 5, lines 16 – 30). Malmqvist indicates that the apparatus utilizes a surface refractive index measurement during operation (see col. 4, lines 21 – 30). The apparatus also comprises computer control and data-processing means (see col. 5, lines 7 – 12).



Regarding claims 6 & 46, Malmqvist teaches that the apparatus comprises a thin gold film (32) having a thickness of about 47 nm within the flow channel (36) (see col. 5, lines 16 – 30; figure 2). Thus, as shown in figure 2, it is inherently anticipated that the gap or channel width would be in the range of between 50 and 1,000 nm. The Courts have held that things clearly shown in a reference patent drawing qualify as prior art features, even though they are unexplained by the specification. See *In re Marz*, 173 USPQ 25 (CCPA 1972).



Regarding claim 18, the apparatus also comprises a prism (16) (see figure 1a).

Regarding claims 19 & 45, Malmqvist indicates that the apparatus can comprise a plurality of flow channels, each comprising a plurality of prisms (see figure 1b).

Regarding claim 42, Malmqvist teaches that the disclosed device incorporates the use of total internal reflection in order to operate (see col. 5, lines 1 – 12). Therefore, it is inherently anticipated that the gap would approximately be equal to or less than the wavelength of the incident light beam.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 35 – 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malmqvist.

Regarding claims 35 – 41, as discussed above, Malmqvist teaches all of the positively recited structure of the apparatus provided in the claimed method, which merely recites the conventional operation of that apparatus. The rationale to support an obviousness rejection under 35 U.S.C. 103 may rely on logic and sound scientific principle (see MPEP § 2144.02). Therefore, it would have been obvious to a person of ordinary skill in the art to perform the method recited in the instant claims upon the apparatus of Malmqvist, as such is the intended operation of that apparatus.

2. Claims 1 – 11, 13 – 17, 20 – 25, 35 – 43 & 46 – 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malmqvist.

Regarding claims 1 – 5, 7 – 11, 13 – 25, 42, 43, 45 & 47 – 50, as indicated in figure 1a, Malmqvist teaches a detection apparatus comprising: a duct, cavity, chamber means or flow channel comprising sidewalls; a glass support (30) coated with a thin gold film (32); a light

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source (LED 10); and a light receiver or optical sensor (photodetector 26) (see figure 1a). The Courts have held that things clearly shown in a reference patent drawing qualify as prior art features, even though they are unexplained by the specification. See *In re Marz*, 173 USPQ 25 (CCPA 1972).

Malmqvist further teaches that the disclosed apparatus is comprised of glass (see col. 5, lines 16 – 30). The Courts have held that the selection of a known material, which is based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of glass in fabricating the disclosed apparatus.

Malmqvist teaches the incorporation of an immobilized binding partner, such as an antibody (38), for detecting target analytes (see col. 5, lines 16 – 30). Malmqvist indicates that the apparatus utilizes a surface refractive index measurement during operation (see col. 4, lines 21 – 30). The apparatus also comprises computer control and data-processing means (see col. 5, lines 7 – 12).

Regarding claims 6 & 46, Malmqvist teaches that the apparatus comprises a thin gold film (32) having a thickness of about 47 nm within the flow channel (36) (see col. 5, lines 16 – 30; figure 2). The Courts have held that things clearly shown in a reference patent drawing qualify as prior art features, even though they are unexplained by the specification. See *In re Marz*, 173 USPQ 25 (CCPA 1972). Therefore, as shown in figure 2, it would have been obvious to a person of ordinary skill in the art to configure the gap or channel width to be in the range of

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between 50 and 1,000 nm. The Courts have held that the size of an article is not a matter of invention. See *In re Rose*, 105 USPQ 237 (CCPA 1955) (see MPEP § 2144.04).

Regarding claim 18, the apparatus also comprises a prism (16) (see figure 1a).

Regarding claims 19 & 45, Malmqvist indicates that the apparatus can comprise a plurality of flow channels, each comprising a plurality of prisms (see figure 1b).

Regarding claim 42, Malmqvist teaches that the disclosed device incorporates the use of total internal reflection in order to operate (see col. 5, lines 1 – 12). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a gap approximately equal to or less than the wavelength of the incident light beam as claimed.

Regarding claims 35 – 41, as discussed above, Malmqvist teaches all of the positively recited structure of the apparatus provided in the claimed method, which merely recites the conventional operation of that apparatus. Therefore, it would have been obvious to a person of ordinary skill in the art to perform the method recited in the instant claims upon the apparatus of Malmqvist, as such is the intended operation of that apparatus.

3. Claims 12 & 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malmqvist in view of Bamdad et al. (U.S. Pat. No. 5,620,850 A) (hereinafter “Bamdad”). Malmqvist does not specifically teach the incorporation of an immobilized chelator with the disclosed sensing device. Bamdad does teach the incorporation of an immobilized cheating agent in a biosensor comprising a surface plasmon resonance chip to facilitate effective sensing (see, e.g., col. 5, lines 26 – 51). The Courts have held that the selection of a known material, which is based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07).

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Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate an immobilized chelator with the disclosed sensing device as claimed.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered, but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Brian J. Sines". The signature is stylized with a large, looping initial "B" and a trailing flourish.